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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,956	09/30/2003	Christopher Don Roberts	355491-1250	1045

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EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	PAPER NUMBER
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,956	ROBERTS ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *April 23, 2006 (amendment)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-7,15-17,23-27 and 30-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-7,15-17,24-27 and 30-33* is/are rejected.

7)☒ Claim(s) *23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3 documents*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims **1-3, 8-14, 18-22 and 28-29** have been cancelled, no claims **4, 6-7,15, 17, 23-24, 27, 30-32** have been amended, the Abstract of the disclosure has been amended, and no new claims have been added as per the amendment filed April 23, 2006. No additional Information Disclosure Statements (IDSs) have been received as of the date of this Office action.

Claims **4-7, 15-17, 23-27 and 30-33** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claim **23** is objected to under 35 C.F.R. §1.75(c), as being in improper dependent form because a claim cannot depend from a cancelled claim. See MPEP §608.01(n). Accordingly, **23** has not been further treated on the merits.

Applicant is referred to the noted claim wherein dependence includes claims **1-3 and 8**, all cancelled claims.

Claims **4-7, 15-17, 24-27 and 30-33** remain under examination in the case.

Applicant's election of **Group I**, claims **4-7** and linking claims **15-17, 24-27 and 30-33** to the degree they remain applicable in Paper No. **08232006** is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

Because applicant has cancelled unelected subject matter and presumably will finish this process in their response to this Office action, Examiner finds the issue of restriction settled in this case.

Claims **4-7, 15-17, 24-27 and 30-33** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has provided at pages 56-69 and 76-79 a total of 9 examples and has provided only exemplary proposed testing of the compounds claimed, but to date has provided no test data in support of the theory that many of the instant claimed compounds has pharmaceutical activity. Examiner notes the instant amendments of claims **4, 6 and 7** wherein generic and functional language found in the original versions of the noted claims has not been made more specific. As a consequence of these amendments applicant has provided a panoramic view of a vast generic class of compounds wherein there is very little synthetic guidance (9 examples) and only prospective guidance in the area of medicinal testing. As a consequence Examiner finds that the written description supports the conclusion that applicant had possession of only a very minor fraction of the subject matter claimed herein. In addition, applicant's terminology in claims **32 and 33** suggesting -- prevention -- (the treatment of "hosts at risk of developing HCV") is completely unsupported by even a prospective testing protocol. Examiner respectfully requests a substantial narrowing of the scope of the instant claimed subject matter in view of the deficiencies in support from the written description.

Applicant's arguments with respect to claims **4-7, 15-17, 24-27 and 30-33** have been considered but are moot in view of the new grounds of rejection.

Claims **4-7, 15-17, 24-27 and 30-33** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being fully enabled for making 9 examples of 6-N-hydroxyl adenine ribonucleosides and nucleotides, does not reasonably provide enablement for the vast array of compounds now claimed with Markush group listings wherein some terms are entirely generic (e.g. "lipids," "carbohydrate," "peptide," :"amino acid," etc.). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: The claims are found to be very broad in light of the numerous variables defined by Markush groups wherein layers upon layers of substituents are defined in some cases with terms suggesting generic classes of substituents and wherein the

terms are not even presented as properly named substituents but only as generic names of classes compounds.

B. The nature of the invention: The invention is directed to adenosine and adenylic acid analogues wherein additional substituents are present at the C-6 amino group, the C-2, and C-8 positions, and at least one hydrocarbyl group at either the 2'- and/or the 3'-carbons of the ribfuranosyl substituent, pharmaceutical compositions thereof, and a method of treating and/or preventing hepatitis C viral (HCV) viral infections in a host in need thereof.

C. The state of the prior art: Some of the instant claimed subject matter has been anticipated, but the 2'-methyl adenosine and adenylic acid analogues are apparently not known in the prior art nor is the administration of these compounds to treat HCV.

D. The level of one of ordinary skill: One of ordinary skill would be knowledgeable in the art of organic synthesis and knowledgeable in the art of determination of medicinally appropriate dosages in the treatment of HCV.

E. The level of predictability in the art: The predictability of the organic synthesis success for compounds closely analogous to the 9 specific exemplifications is high, but this predictability diminishes in an unpredictable manner as the number of substituents increases. In light of the total absence of data concerning the medicinal applicability of the instant claimed compounds to the treatment of any disease conditions, predictability is very low.

F. The amount of direction provided by the inventor: The instant disclosure provides only 9 synthetic exemplifications for purine nucleosides and nucleotides and only prospective examples for medicinal testing.

G. The existence of working examples: This topic is discussed in the previous paragraph.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive both synthetically and medicinally in view of the very small number of examples and the vast number of claimed embodiments, and in view of the total absence of any medical testing data. Examiner also notes that pharmaceutical

compositions containing mixtures of active ingredients or the medicinal administration thereof to treat HCV is also clearly not enabled.

Applicant's arguments with respect to claims **4-7, 15-17, 24-27 and 30-33** have been considered but are moot in view of the new grounds of rejection.

Claims **4-7, 15-17, 24-27 and 30-33** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **4** at line 20, the group NR^3R^4 wherein R^3 and R^4 may be "alkenyl" or "alkynyl" are unlikely to be stable or easily isolable, suggesting that many of the Markush group members are selected as boilerplate, not as examples likely to have any utility. Examiner respectfully requests major pruning of the instant claim and inthe remaining claims wherein there are extensive listings of substituents (claims **6 and 7**) to eliminate the obvious deadwood.

Applicant's arguments with respect to claims **4-7, 15-17, 24-27 and 30-33** have been considered but are moot in view of the new grounds of rejection.

In claim **4** at lines 54-64, a Markush group has been defined with the generic names of classes of compounds, or of compounds, as opposed to names of specific substituents. Compounds are not substituents, an obvious technical error. See also claims **6 and 7** for the same problem.

Applicant's arguments with respect to claims **4-7, 15-17, 24-27 and 30-33** have been considered but are moot in view of the new grounds of rejection.

In claim **4** at line 68, the term "and or" at the end of the line suggests confusion concerning proper format for an alternative listing. Examiner suggests cancellation of the term " and."

In claim **6** at line 53, the term "(-S or R Inactive)" includes an inappropriate capitalization and is unclear concerning what applicant has intended to claim. The term "[alpha]-D-ribofurnaosyl" entirely defines the stereochemical choices and therefore what additional diastereomeric or enantiomeric limitations are possible is unclear to examiner. Clarification and/or explanation is respectfully requested.

Applicant's arguments with respect to claims **4-7, 15-17, 24-27 and 30-33** have been considered but are moot in view of the new grounds of rejection.

In claims **32 and 33** the term "host" is incomplete and should be amended to read -- host in need thereof --.

Applicant's arguments with respect to claims **4-7, 15-17, 24-27 and 30-33** have been considered but are moot in view of the new grounds of rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

(f) he did not himself invent the subject matter sought to be patented."

Claims **4, 24-26 and 31** are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Knutsen et al. '027** (PTO-892 ref. **E**)..

Applicant is referred to columns 12-16, titled Example compounds 4-9 and 12 and at column 17-18 see claims ***1-2, 4-7, 9, and 12-15*** wherein the instant claimed subject matter has been anticipated.

Applicant's arguments with respect to claims **4, 24-26 and 31** have been considered but are moot in view of the new grounds of rejection.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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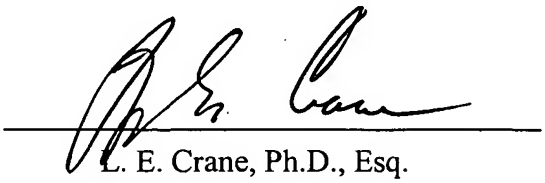

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